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### REMARKS

Reexamination and reconsideration in light of the foregoing amendments and following remarks is respectfully requested.

Claims 13, 15 and 17 are pending. Claims 13, 15 and 17 have been rejected.

#### II. CLAIM REJECTIONS UNDER 35 U.S.C. § 102

With respect to the rejection of claims 13 and 15 under 35 U.S.C. § 102(b) as anticipated by DE 19841615 (the "'615 Abstract"), JP 04202138 (the "'138 Abstract") or JP 406312924 (the "'924 Abstract"), Applicant traverses for the following reasons.

The invention lies in the discovery that COX-2 inhibitors having a prescribed  $IC_{50}$ -WHMA COX-2/COX-1 ratio are (a) better *in vivo* COX inhibitors because of their COX-2 selectivity; and are (b) pharmaceutically superior to known compositions because of their reduced gastrointestinal and cardiovascular toxicity.

The inventor has identified hops extracts which are enriched for COX-2 inhibitors associated with the prescribed  $IC_{50}$ -WHMA COX-2/COX-1 ratio. As taught in the Application as filed at paragraph [0024], iso-alpha acids are better *in-vivo* COX inhibitors with a COX-2 selectivity and a side-effect profile that is superior to the same dose of unisomerized hop extract.

Iso-alpha acids are not found in hops absent further chemical modification or processing. The  $IC_{50}$ -WHMA COX-2/COX-1 ratio is not taught by any of the cited art. Natural hops compositions do not produce the ratio required according to claims 13 and 15. Thus, the claimed ratio may not be "inherent to the composition of hops" (see Office Action at page 3).

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The '615 Abstract describes the use of wine extracts of a number of plants including among others, hops. Notably, a wine extract of hops will not contain iso-alpha acids insofar as the extraction with wine will not chemically produce an iso-alpha acid from alpha acids.

The '138 Abstract sets forth hops extracts (for the treatment of malignant rheumatoid arthritis, burns and skin disease) obtained using one or two solvents to obtain lupulonic acid, colupulone, and adlupulone) the methods do not encompass known methods to convert alpha acids into iso-alpha acids (e.g., acidic pH treatment in the presence of excessive heat or photo-irradiation).

The '924 Abstract describes compositions of humulone, cohumulone, humulone, and adhumulone obtained by the Wollmer's method which do not contain iso-alpha acids insofar as the Wollmer's method will not chemically produce an iso-alpha acid from alpha acids.

Accordingly, Applicant respectfully request reconsideration and withdrawal of the rejections in light of the amendments and remarks found herein.

With respect to the rejection of claims 13, 15, and 17 under 35 U.S.C. § 102(e) as anticipated by Newmark *et al.*, or Babish *et al.* Applicant traverses for the following reasons.

Newmark *et al.* and Babish *et al.* do not seek to identify compositions with reduced gastro-and cardio toxicity. Applicant's claimed invention does. Assuming *arguendo*, that the prescribed IC<sub>50</sub>-WHMA COX-2/COX-1 ratio according to claims 13, 15, and 17 is inherent to hops compositions according to Newmark *et al.* and Babish *et al.*, neither Newmark *et al.* nor Babish *et al.* have selected those compositions which are

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associated with reduced gastro-and cardio toxicity. Accordingly, neither Newmark *et al.* nor Babish *et al.* may anticipate claims 13, 15 and 17.

<<CONCLUSION SECTION ON THE NEXT PAGE>>

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### III. CONCLUSION

On the basis of the foregoing remarks and amendments, Applicants respectfully submit that amended claims 13, 15 and 17 are in condition for allowance. Passage to issue is respectfully requested.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicant's attorney at the telephone number shown below.

A Request for a Three (3) Month Extension of Time, up to and including September 25, 2006 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications, to Deposit Account 50-1133. Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under paragraph 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate length of time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectfully submitted,  
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